IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM INTERNATIONAL GMBH and BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	
Plaintiffs,	**C.A. No._____**
v.	
MYLAN PHARMACEUTICALS INC.,	
Defendant.	

COMPLAINT

Plaintiffs Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. (hereinafter "Plaintiffs" or "Boehringer"), for their Complaint herein against defendant Mylan Pharmaceuticals Inc., allege as follows:

PARTIES

1. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a corporation organized and existing under the laws of Germany, having an office and place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

2. Plaintiff Boehringer Ingelheim Pharmaceuticals, Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877.

3. On information and belief, Mylan Pharmaceuticals Inc. ("Mylan") is a corporation incorporated under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26504. Mylan describes

itself as "the #1 US-based manufacturer of generic pharmaceutical products" and claims that during 2004, "pharmacists filled more than 197 million prescriptions with products from Mylan." On information and belief, a proportionate number of those prescriptions were filled in Delaware, and during 2004, more generic prescriptions issued in Delaware were filled with Mylan products than from any other US-based generic manufacturer.

4. Mylan has availed itself of the jurisdiction of this Court in connection with the litigation of patent disputes. For example, in 2002, Mylan filed Civil Action No. 02-1628-GMS in this Court concerning the alleged infringement of a patent licensed to Mylan concerning generic omeprazole, and earlier this year filed counterclaims in Civil Action No. 05-371-KAJ in this Court seeking declaratory judgments of noninfringement and invalidity of a patent.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Mylan is subject to the jurisdiction of this Court because, *inter alia*, it sells various products and does business throughout the United States, including within this judicial district, it regularly does business in Delaware and derives substantial revenue from things used or consumed in Delaware, and because it has purposefully availed itself of the privileges of conducting business within Delaware such that Mylan should reasonably anticipate being haled into court as a result of its conduct and connection with Delaware.

7. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(c) and 28 U.S.C. § 1400(b).

BACKGROUND

8. United States Patent No. 4,886,812 ("the '812 patent"), entitled "Tetrahydro-Benzthiazoles, The Preparation Thereof and Their Use as Intermediate Products or as Pharmaceuticals," was duly and legally issued on December 12, 1989 to Dr. Karl Thomae GmbH of Biberach an de Riss, Germany, the assignee of the named inventors, Gerhart Griss, Claus Schneider, Rudolf Hurnaus, Walter Kobinger, Ludwig Pichler, Rudolf Bauer, Joachim Mierau, Dieter Hinzen and Gunter Schingnitz. Plaintiff BII is the record owner of the '812 patent. Plaintiff BIPI is a licensee under the '812 patent. A true and correct copy of the '812 patent is attached as Exhibit A.

9. On July 1, 1997, the United States Food and Drug Administration ("FDA") approved new drug application ("NDA") No. 20-677 for MIRAPEX®, a pharmaceutical composition containing pramipexole dihydrochloride, under § 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 335(a), for the treatment of the signs and symptoms of idiopathic Parkinson's disease. Boehringer is the holder of approved NDA No. 20-667 for pramipexole dihydrochloride tablets, which are sold under its trademark MIRAPEX®.

10. The publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. BII listed the '812 patent in the Orange Book for its MIRAPEX® products.

11. On information and belief, Mylan submitted to the FDA abbreviated new drug application ("ANDA") No. 77-854 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of pramipexole dihydrochloride

tablets in the 0.125, 0.25, 0.5, 1.5 and 1 mg strengths as a generic version of the MIRAPEX® 0.125, 0.25, 0.5, 1.5 and 1 mg products.

12. By way of a letter dated October 26, 2005 (the "Mylan Letter"), Mylan advised Boehringer that it had submitted ANDA No. 77-854 seeking approval to engage in the commercial manufacture, use and/or sale of generic versions of MIRAPEX® prior to the expiration of the '812 patent.

13. The Mylan Letter also advised Boehringer that Mylan's ANDA included a certification under 21 U.S.C. § 355(j)(2)(vii)(IV) that, in Mylan's opinion, claims 1-5 and 7-10 of the '812 patent are invalid and that the products described in Mylan's ANDA will not infringe claim 6 of the '812 patent.

CLAIM FOR RELIEF

14. Plaintiffs incorporate each of the preceding paragraphs 1 to 13 as if fully set forth herein.

15. By filing ANDA No. 77-854 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of generic MIRAPEX® before the expiration of the '812 patent, Mylan has committed an act of infringement of the '812 patent under 35 U.S.C. § 271(e)(2).

16. On information and belief, Mylan acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '812 patent.

17. Mylan's ANDA and Paragraph IV certification are premised upon a baseless assertion that the claims of the '812 patent are invalid under 35 U.S.C. § 103. Mylan disregarded its duty to exercise due care and committed an act of infringement premised on this baseless assertion of invalidity, rendering Mylan's infringement of the '812 patent willful. This

case is therefore an exceptional one, and Boehringer is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

18. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 77-854 be deemed not earlier than the March 25, 2011 expiration date of the '812 patent and an injunction precluding Mylan from infringing the '812 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Mylan has infringed the '812 patent;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4)(a) that the effective date of any approval of Mylan's ANDA No. 77-854 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C § 355(j)) be a date which is not earlier than the expiration date of the '812 patent;

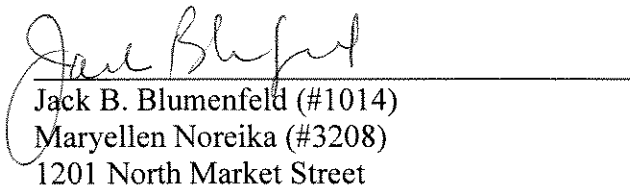
C. A permanent injunction be issued, pursuant to 35 U.S.C § 271(e)(4)(B), restraining and enjoining Mylan and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '812 patent for the full term thereof;

D. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

E. Costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL



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